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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,946.	08/08/2001	Mark J. Evans	0630/1G703US2	3104
7278	7590	10/20/2004	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,946

Applicant(s)

EVANS ET AL.

Examiner

Yong D Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 45-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 16, 21-41, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 13-15, 17-20, 47-53 and 55 is/are rejected.
- 7) ☒ Claim(s) 11, 12 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 26, 2004, amending claims 18-20 and 26 and canceling claims 42-44, has been entered.

Claims 1-41 and 45-55 are pending.

Election/Restrictions

Claims 1-7, 16, 21-41 and 45-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Response to Arguments

Applicant's arguments filed July 26, 2004, with respect to the objection of claim 19 have been fully considered and are persuasive. The objection of claim 19 has been withdrawn.

Applicant's arguments with respect to claims 18-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 13-15, 17, 47-53 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-10, 13-15, 17, 47-53 and 55 are drawn to DNA encoding a EER-7 protein that is at least 75-90% identical to SEQ ID NO:2 and wherein the protein comprises of four scavenger receptor cysteine rich domains having at least 80-90% sequence identity to SEQ ID NOs: 3, 4, 5 and 6. A description of only 75-90% of the structure of the DNA encoding an EER-7 protein, amounts to an insufficient description of the structure of the DNA molecule in this claim. The genus of DNA that comprise the above variants is a large variable genus with the potentiality of encoding many different proteins. Therefore, these claims are drawn to a large variable genus of DNA molecules encoding polypeptides with an insufficient limitation on structure. The specification teaches DNA encoding the EER-7 of SEQ ID NO:2. However, many structurally unrelated DNA are encompassed within the scope of these claims. The specification fails to describe any other representative species by any identifying characteristics or

properties other than the "functionality" of encoding a EER-7 and fails to provide any structure: function correlation present in all members of the claimed genus.

Claims 18-20 are drawn to an oligonucleotide of no more than 100 nucleotides comprising at least 20-30 consecutive nucleotides of SEQ ID NO:1 and hybridizing to SEQ ID NO:1. A description of any 20-30 consecutive nucleotide bases out of 3616 nucleotides of SEQ ID NO:1, which represents less than 1/3 of the whole structure of the oligonucleotide and less than 1% of the whole structure of SEQ ID NO:1, amount to insufficient description of the structure of the oligonucleotides in the claims. Further, the oligonucleotide can hybridize to any portion of SEQ ID NO:1. Therefore, these claims are drawn to a genus of oligonucleotides, with any structure. The genus of DNA that comprise these above fragments and portions of SEQ ID NO:1 is a large variable genus. Many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences, encompassing a variety of species with widely varying attributes. The specification fails to describe any other representative species by any identifying characteristics or properties other than comprising of 20-30 consecutive nucleotides SEQ ID NO:1 and hybridizing to any portions of SEQ ID NO:1 and fails to provide any structure: function correlation present in all members of the claimed genus.

Claims 8-10, 13-15, 17, 47-53 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the EER-

7 of SEQ ID NO:2, does not reasonably provide enablement for DNA molecules of unlimited structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims encompass molecules having very low structural similarity to SEQ ID NO:1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims. The claims are drawn to polynucleotides comprising at least 20 nucleotide bases that hybridize to any portion of SEQ ID NO:1. A polynucleotide of 20 nucleotide bases will hybridize to a wide range of polynucleotide and the specification does not teach how to use these varying polynucleotides/oligonucleotides. Claims are also drawn to polynucleotides encoding an EER-7 protein having 75-90% homology to SEQ ID NO:2. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other EER-7 is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of polynucleotides where the expectation of obtaining similar sequences is unpredictable. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen a large number of possible combinations. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make DNA encoding a EER-7 protein different from SEQ ID NO:2 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Response to Amendment

The affidavit filed on July 26, 2004 under 37 CFR 1.131 is sufficient to overcome the Meyers et al. (U.S. Patent Application Publication No. 2003/0059919) reference.

Allowable Subject Matter

Claims 11-12 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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